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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/905,370	07/12/2001	Preeti G. Lal	PF-0802 US	3719

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EXAMINER
SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
1652	12

DATE MAILED: 11/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/905,370	LAL ET AL.	
	Examiner	Art Unit	
	Elizabeth Slobodyansky	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7,9,11,13-15,27,28 and 46-51* is/are pending in the application.

4a) Of the above claim(s) *1,2,13-15,27 and 28* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,6,7,9,11 and 48-51* is/are rejected.

7)☒ Claim(s) *4 ,5, 46 ,47* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8* .
4)☐ Interview Summary (PTO-413) Paper No(s). _____ .
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The amendment filed September 23, 2002 (Paper No. 11) amending claims 1, 3, 4, 9, 27 and 51 has been entered.

Claims 1-7, 9, 11, 13-15, 27, 28 and 46-51 are pending.

Election/Restriction

Applicant's election with traverse of Group II in Paper No. 11 is acknowledged. The traversal is on the ground(s) that "Claims directed to methods of using the claimed polynucleotides ... could and should be examined together with the product claims" (Remarks, page 6). This is not persuasive because the methods claims are restricted for the proper reasons indicated in the Office action mailed September 4, 2002. The issue of rejoinder will be revisited when the product claims will become allowable. Applicants further argue that "Claims 1 and 2, drawn to polypeptides of the invention, could be examined along with the polynucleotide claims without undue burden on the Examiner. A search of the prior art to determine the novelty of the polynucleotides would substantially overlap with a search of the prior art to determine the novelty of the polypeptides encoded by the polynucleotides" (page 6). This is not found persuasive because establishing the novelty of polypeptides would require more information than can be provided by the search of a polynucleotide. It would also require divergent considerations.

The requirement is still deemed proper and is therefore made FINAL.

Claims 1, 2, 13-15, 27 and 28 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected Groups I, III and IV, the requirement having been traversed in Paper No. 11.

Claims 3-7,9, 11 and 46-51 are under consideration.

Specification

The specification is objected to because it contains references to the tables that are not included in the disclosure. These tables are presented as separate entities.

There is "brief description of the tables" on page 7. If Applicants consider said tables as drawings they should designate them as "Figures" and they will be subjected to Draftsman review. If Applicants intend to have tables that are not drawings they should include them into the disclosure.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to the drawings, each of the lettered items should appear in upper case, without underling or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.

(b) Cross-Reference to Related Applications.

(c) Statement Regarding Federally Sponsored Research or Development.

(d) Reference to a "Sequence Listing," a table, or a computer program listing appendix submitted on compact disc (see 37 CFR 1.52(e)(5)).

(e) Background of the Invention.

1. Field of the Invention.

2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.

(f) Brief Summary of the Invention.

(g) Brief Description of the Several Views of the Drawing(s).

(h) Detailed Description of the Invention.

(I) Claim or Claims (commencing on a separate sheet).

(j) Abstract of the Disclosure (commencing on a separate sheet).

(k) Drawings.

(l) Sequence Listing, if on paper (see 37 CFR 1.821-1.825).

Claim Objections

Claims 48-50 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 48 depends from claim 3. Claims 49 and 50 depend from claim 11.

Claims 3 and 11 are limited to naturally-occurring variants while dependent claims encompass any variants.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 6, 7, 9, 11 and 48-51 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 3(b), with dependent claims 6, 7 and 9, is drawn to a DNA encoding a naturally-occurring variant that is 98% identical to SEQ ID NO:1 and a DNA comprising an immunogenic fragment of SEQ ID NO:1. Claim 48 is drawn to a DNA encoding a variant that is 98% identical to SEQ ID NO:1. Claim 11(b) is drawn to a naturally-occurring DNA that is 90% identical to SEQ ID NO:2. Claims 49 and 50 are drawn to a DNA that is 95% and 90% identical to SEQ ID NO:2, respectively. Claim 51 recites a DNA comprising 750 contiguous nucleotides of SEQ ID NO:2. Therefore the claims are directed to a diverse genus of variants of a DNA encoding SEQ ID NO:1. This genus includes many structurally and functionally unrelated DNAs.

Naturally occurring nucleotide sequence having at least 90% identity to SEQ ID NO: 2 or encoding an amino acid sequences having at least 98% identity to SEQ ID NO:1, includes allelic variants of SEQ ID NO:1, and all other loci which encode proteins having 98% identity to SEQ ID NO:1. The function of these variants **may or may not be altered**. The genus of claims 48-50 include both naturally-occurring and man made variants having the function of SEQ ID NO:1, those which lack such activity as well as an enormous number of polypeptides with undisclosed functions. As such, neither the description of the structure and function of a DNA encoding SEQ ID NO:1 nor the disclosure solely structural features present in all members of the genus is sufficient to be representative of the attributes and features of the entire genus.

Thus, a DNA encoding a polypeptide comprising a variant of SEQ ID NO:1 having undisclosed function or a DNA that is 90% identical to SEQ ID NO:2 encoding a polypeptide of undisclosed function lack sufficient written description needed to practice the invention of claims 3, 6, 7, 9, 11 and 48-51.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 3, 6, 7, 9, 11, 13 and 48-51 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a DNA encoding SEQ ID NO:1, does not reasonably provide enablement for a DNA encoding an immunogenic fragment thereof, a polypeptides having certain percent identity thereto with unknown functions and to a DNA comprising 750 nucleotides of SEQ ID NO:2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification does not reasonably provide enablement for a DNA encoding a polypeptide retaining the function of SEQ ID NO:1 that comprises 750 nucleotides of SEQ ID NO:2 or comprises an immunogenic fragment of SEQ ID NO:1.

Factors to be in In re Wands 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988). They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7)considered in determining whether undue experimentation is required, are summarized the predictability or unpredictability of the art, and (8) the breadth of the claims.

The specification does not support the broad scope of the claims which encompass all modifications and fragments of any sequence that comprises a fragment of SEQ ID NO:1 or is 98 % identical to the specific amino acid sequence of SEQ ID NO:1 because the specification does **not** establish: (a) regions of the protein structure which may be modified without effecting the specific requisite activity of the polypeptide of the instant invention; (B) the general tolerance of said polypeptide to modification and extent of such tolerance; (C) a rational and predictable scheme for modifying any amino acid residues with an expectation of obtaining the desired biological function; and (D) the specification provides insufficient guidance as to which of the essentially infinite possible choices is likely to be successful.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable

correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of polypeptide structure having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue.

Furthermore, the claims encompasses DNAs encoding polypeptide having no known functions. The specification does not teach how to use said inactive variants. Therefore, the breadth of these claims is much larger than the scope enabled by the specification.

The state of the art does not allow the predictability of the properties based on the structure. Therefore, one skilled in the art would require guidance as to how to use a DNA encoding a polypeptide of unknown function having 98% identity to SEQ ID NO:1 or comprising an immunogenic fragment of SEQ ID NO:1. One skilled in the art would require guidance as to how to use a DNA that is 90% identical to SEQ ID NO:2 or comprises 750 nucleotides thereof and encodes a polypeptide that has no function in a manner reasonably correlated with the scope of the claims. Without such guidance, the experimentation left to those skilled in the art is undue.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 is indefinite because it is unclear whether "encoding" is open or closed language. In other words, it is unclear whether a DNA encoding an immunogenic fragment, for example, can encode other sequences.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> a person shall be entitled to a patent unless -
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 3, 6, 7, 9, 11 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Hayashi et al.

Hayashi et al. teach SEQ ID NO:1, a DNA encoding human cytochrome P450 1A2 having the amino acid sequence that is 99.3% identical to SEQ ID NO:1, a vector containing it and a cell expressing thereof.

Claim 3, 6, 7, 9 and 48-51 are rejected under 35 U.S.C. 102(b) as being anticipated by Jaiswal et al.

Jaiswal et al. (GenBank accession Z00036, form PTO-1449, references 3, 18, 24) teach a DNA encoding human cytochrome P3(450) that is 93.6% identical to SEQ ID NO:2, a vector containing it and a cell expressing thereof.

Allowable Subject Matter

Claims 4,5, 46 and 47 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.

E. Slobodyansky

Elizabeth Slobodyansky, PhD
Primary Examiner

November 15, 2002